Conclusion: This study provides valuable insights in the patient perspective on a PRO-based drug safety monitoring system for inflammatory rheumatic diseases and other IMIDs, and provides several useful starting points to further stimulate and improve PRO-based CEM systems. Altogether, it appears feasible to establish a PRO-based drug safety monitoring system that monitors IMID patients' real-world experience with ADRs that has a low burden for the participants.

Disclosure of Interests: Leanne Kossé: None declared, Gerda Weits: None declared, Harald Vonkeman Conflict of interest from: Abbvie, AstraZeneca, BMS, Celgene, Cetilrior, Galapagos, Gilead, GSK, Janssen-Cilag, Lilly, MSD, Novartis, Pfizer, Roche, Sanofi-Genzyme, all outside the submitted work., Sander Tas Grant/research support from: Abbvie, AstraZeneca, BMS, Celgene, Galapagos, GSK, MSD, Pfizer, Roche, Sanofi-Genzyme, all outside the submitted work., Frank Hoentjen Speakers bureau: Abbvie, AstraZeneca, BMS, Celgene, Cetilrior, Galapagos, Gilead, GSK, Janssen-Cilag, Lilly, MSD, Novartis, Pfizer, Roche, Sanofi-Genzyme, all outside the submitted work., Miikael Nurmohamed Speakers bureau: Abbvie, AstraZeneca, BMS, Celgene, Cetilrior, Galapagos, Gilead, GSK, Janssen-Cilag, Lilly, MSD, Novartis, Pfizer, Roche, Sanofi-Genzyme, all outside the submitted work., Michael Nurmohamed Grant/research support from: Janssen, MSD, Novartis, Pfizer, Sanofi-Genzyme, all outside the submitted work., Hans Van den Bergh Conflict of interest from: Abbvie, AstraZeneca, BMS, Celgene, Cetilrior, Galapagos, Gilead, GSK, Janssen-Cilag, Lilly, MSD, Novartis, Pfizer, Roche, Sanofi-Genzyme, all outside the submitted work., Naomi Jessurun: None declared.

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We developed a cross-sectional open survey following the rationale of the Technology Acceptance Model to obtain insight in patients’ perspectives on the DBM. The DBM is a pilot for a PRO-based drug safety monitoring system for immun-mediated inflammatory diseases (IMID) including Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), spondyloarthritis (SpA), and Inflammatory Bowel Disease (IBD). The DBM involves a mixed method approach; quantitative and qualitative methods were used to obtain an insight in patients’ perspectives on the DBM. Twenty-four respondents (15.8%) reported a burden of medium, 25 respondents (18.9%) reported a burden of high, and 10 respondents (7.6%) reported a burden of very high. The remaining 85 respondents (65.7%) reported a burden of low or no burden or no answer.

Background: The burden of PROs on adverse drug reactions (ADRs) is increasing in rheumatology and other medical specialties. The burden of ADRs can be determined using patient-reported outcome measures such as the Patient-Reported Outcome Measures Information System (PROMIS). The PROs on ADRs can impact patient compliance, quality of life, and real-world experience with ADRs.

Methods: We developed a cross-sectional open survey following the rationale of the Technology Acceptance Model to obtain insight in patients’ perspectives on the DBM. We developed a questionnaire for the survey based on the Technology Acceptance Model and included questions on burden, perceived usefulness, ease of use, and attitude toward using the Dutch Biologic Monitor (DBM). The survey consisted of 20 questions on the burden of ADRs on different aspects of daily life, such as personal activities, work, social life, and health care.

Results: The survey was completed by 292 respondents (65.7% male, mean age 50.2 years). The majority of respondents (173 respondents, 59.2%) reported a burden of medium, 96 respondents (32.8%) reported a burden of high, and 23 respondents (7.8%) reported a burden of very high. The remaining 10 respondents (3.4%) reported a burden of low or no burden or no answer.

Conclusions: The results of this study provide valuable insights into the patient perspective of the burden of ADRs on different aspects of daily life. The results of this study can be used to improve the PRO-based drug safety monitoring system and other CEM systems. The results of this study can also be used to improve the Design for a National Drug Safety Monitoring System (DBM) and improve PRO-based CEM systems. Altogether, it appears feasible to establish a PRO-based drug safety monitoring system that monitors IMID patients’ real-world experience with ADRs that has a low burden for the participants.

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